

REMARK

Appreciation is hereby expressed to Examiner Lam for the telephone interview so courteously and professionally conducted on September 2, 2004. In accordance with the discussions held therein, Claims 1, 4 and 7 have been cancelled, and claims 2, 3, 5 and 6 have been amended to more definitely set forth the invention and obviate the rejections. Support for these amendments can be found in now cancelled claims 1 and 4. The present amendment is deemed not to introduce new matter. Claims 2, 3, 5 and 6 are in the application.

Reconsideration is respectfully requested of the rejection of claim 1-7 under 35 U.S.C. §102(e) as being anticipated by McNichols, et al. (USP 5,047,007).

The cited McNichols, et al. reference discloses a method and apparatus for pulsed iontophoretic drug delivery. A primary objective of the McNichols, et al. device is to increase the quantity of ionic drug being delivered transdermally throughout each therapeutic pulse by reducing the charging time of the capacitive component of the skin  $C_p$  during the initial portion of each therapeutic pulse (see col. 7, lines 20-25). In contrast, it is an object of the present invention to provide a device for iontophoresis capable of determining conduction states with a high level of accuracy (see Specification, page 3, lines 7-10), and is NOT positioned directly between the electrodes 116 and 118.

The cited McNichols, et al. reference describes said apparatus as having a feedback circuit 122b including a sensor-feedback means for sensing a potential at active electrode 116 during each first pulse segment (see column 14, lines 39-42), and it is not coupled to an indifferent electrode 118. Furthermore, there is a discharge circuit 128 between the electrodes 116 and 118, but it is

provided for discharging or depolarizing an unwanted potential which can develop during each therapeutic pulse across the electrodes 116 and 118 and skin load SL disposed therebetween (see column 16, line 50-55).

In particular, the sensor-feedback circuit 122 of the McNichols, et al. device comprises a feedback compare circuit 122b, which compares a first potential presented at the non-inverting terminal of comparator 140, which first potential comprises the threshold potential coupled along line 138 (as shown in Appendix 3 attached hereto), with a second potential presented at the inverting terminal of comparator 140, which second potential corresponds to a potential sensed at the active electrode 116 during each first pulse segment (see column 14, lines 28-52, and Appendix 3 attached hereto). This potential sensed at the electrode 116 does NOT correspond to the residual voltage or the reactive current, as detected in the present invention, as it is sensed "during each first pulse segment", NOT "during an off-period of an output", as claimed herein.

The sensor-feedback means of the McNichols, et al. reference CANNOT detect a reactive current or a residual voltage because a potential sensed at the active electrode 116 during each first pulse segment is only compared with the threshold potential coupled along line 138 (as shown in Appendix 3 attached hereto) at comparator 140 and the output of comparator 140 is led to the gate of MOSFET T1 (also as shown in Appendix 3 attached hereto). As a result, according to the description in column 15, lines 5-11, "MOSFET T1 will thus continue to gate the supply voltage to voltage gate circuit 124 during the initial portion of each therapeutic pulse until the output from comparator 140 assumes a low output state causing MOSFET T1 to become biased off, which event will occur when the potential at the active electrode 116 exceeds the threshold potential".

Thus, it is believed that the McNichols, et al. reference discloses neither the device claimed herein, nor the method of detecting residual voltage developed by the charge remaining in a capacity component of impedance of the transdermal or the transmucosal tissue based on a voltage existing between the output terminals **during an off-period of an output**, as claimed herein. Rather, this device and method are believed to be taught only by the present invention, and constitute important elements or aspects thereof.

Importantly, the feedback compare circuit 112b of the McNichols, et al. reference *compares* a first potential presented at the non-inverting terminal of comparator 140 with a second potential presented at the non-inverting terminal of comparator 140. Thus, as discussed with Examiner Lam at the interview, contrary to the Examiner's assertions on page 4, second paragraph, of the instant Office Action, the feedback compare circuit 122b is NOT a switch, or equivalent to a switch, as is claimed herein. Likewise, resistors R5 and R6 are NOT equivalent to the resistors claimed herein, as they are not coupled to the negative output terminal (i.e., 114D as shown in FIG. 3), and thus differ greatly from the resistors claimed in claims 2 and 5 herein.

As also discussed with Examiner Lam during the interview, the capacitor C2 of the McNichols, et al. reference is not equivalent to the capacitor claimed herein, as the capacitor C2 of the McNichols, et al. reference is not believed to be able to smooth out the waveform across the switch. Further, there is believed to be no other element provided by McNichols, et al. that does or is capable of smoothing out the waveform across the switch, as performed by the capacitor claimed herein. For example, the capacitor C5, rather, functions "as a means for discharging or depolarizing an unwanted potential which can develop during each therapeutic pulse across the electrodes 116 and

118 and skin load  $S_L$  disposed therebetween" (see column 16, lines 52-55), and is not coupled to the base terminal of transistor T3.

Moreover, unlike the McNichols, et al. reference, the present invention includes:

"(a) a detection circuit for detecting reactive current flowing through a capacity component of impedance of the transdermal or the transmucosal tissues based on current outputted from the negative output terminal; and/or

(b) a detection circuit for detecting residual voltage developed by the charge remaining in a capacity component of impedance of the transdermal or the transmucosal tissue based on a voltage existing between the output terminals during an off-period of an output".

It is believed that the McNichols, et al. device fails to perform this function. Further, the McNichols, et al. specification fails to state that the first pulse segment generator means 20 and second pulse generator means 22 (column 10, lines 25-31) can function in the same way as the claimed first circuit herein. Hence, said elements CANNOT be deemed to be equivalent to the first circuit claimed herein in either STRUCTURE OR FUNCTION. Thus, contrary to the Examiner's assertion, it is believed that the McNichols, et al. reference fails to disclose the first circuit as now claimed herein.

Furthermore, importantly, claims 2 and 5 as amended call for a switch for sending one of positive and negative waveforms of current from the resistor, as illustrated in Figure 7 as element 50. In particular, it is believed, contrary to the Examiner's assertions in paragraph 2 on page 4 of the instant Office Action, that transistor T3 of McNichols, et al. does not correspond to the switch 50 claimed herein because transistor T3 does not send one of positive and negative waveforms from the

resistor R15 in the McNichols, et al. reference. As described in column 16, lines 65-68, of McNichols, et al., "transistor T3 as a switch is in an "on" state to enable discharge therethrough during each pulse interval and in an "off" state during each pulse width". That is, transistor T3 does not send one of positive and negative waveforms of current from the resistor R15, as is claimed herein.

With regards to claims 3 and 6, the Examiner has pointed to column 14, lines 28-43 of the McNichols, et al. reference, to provide disclosure of the claimed detection circuit having a discharging resistor coupled between the output terminals for detecting the residual voltage. However, it is believed that McNichols fails to disclose such a claimed element, which constitutes an important element or aspect of the present invention. Specifically, as illustrated in Figure 3 of the McNichols, et al. reference, there is no provision of a discharging resistor between output terminals 114C and 114D, as is claimed herein.

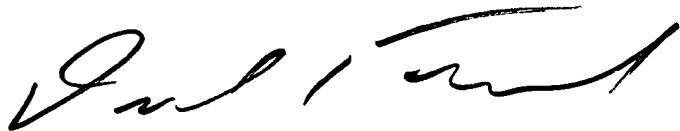
Rather, it is believed that McNichols, et al., in fact, do not disclose a discharging resistor *coupled between output terminals* as claimed herein. In particular, a "discharging resistor" is a resistor that allows a residual voltage to discharge. A "residual voltage" is voltage developed by the charge remaining in a capacity component of impedance of the transdermal or transmucosal tissue based on a voltage existing between the output terminals during an off-period of the output (as described in claim 1). Such a resistor must be positioned between the output terminals. However, the resistor referred to by the Examiner is NOT positioned between the output terminals and, thus, is incapable of performing in the claimed manner.

In view of the deficiencies of the cited McNichols, et al. reference, as discussed above, it is believed that the McNichols, et al. fails to anticipate or render the present invention unpatentable. As such, withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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